The purpose of this worksheet is to provide support for physicians conducting an emergency use of an unapproved drug, biologic, or device in a life-threatening situation, or compassionate use of an unapproved device that does not have an Investigational Device Exemption (IDE), and to provide support to designated reviewers reviewing such uses. This worksheet, or equivalent, is to be used when evaluating such uses. It does not need to be completed or retained.

Emergency Use of an Unapproved Drug or Biologic[1]

1 Exemption Criteria for Emergency Use of an Unapproved Drug or Biologic (Check if **"Yes."** All must be checked)

- ☐ The patient is (was) confronted by a disease or condition that is (was) either:
  - ☐ Life-threatening (diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted and diseases or conditions with potentially fatal outcomes, where the end point of clinical trial analysis is survival).
  - ☐ Severely debilitating (diseases or conditions that cause major irreversible morbidity).
- ☐ The situation necessitates (necessitated) the use of the investigational drug or biologic.
- ☐ No generally acceptable alternative for treating the patient is (was) available.
- ☐ There is (was) insufficient time to obtain IRB approval.
- ☐ The treating physician will document (has documented) in the medical record that the above findings were met.
- ☐ The treating physician will report (has reported) the use to the IRB within 5 days with documentation that the above findings were met.
- ☐ The Food and Drug Administration (FDA) has (had) issued an investigational new drug (IND).
- ☐ The use is (was) **NOT** subject to Department of Health and Human Services (DHHS) regulation.[2] See *OIA-310 WORKSHEET: Human Research Determination*, or equivalent.

Section 2 or 3 must be met

2 Consent Criteria (Check if **"Yes."** All must be checked)

- ☐ Informed consent will be (was) sought from the patient or the patient's legally authorized representative (LAR), in accordance with and to the extent required by 21 CFR Part 50. See *OIA-314B WORKSHEET: Requirements for Informed Consent*, or equivalent.
- ☐ Informed consent will be (was) documented using *OIA-506 TEMPLATE CONSENT DOCUMENT: Expanded Access*, or equivalent, in accordance with and to the extent required by 21 CFR 50.27. See *OIA-314 WORKSHEET: Criteria for Approval and Additional Considerations*, or equivalent.

3 Exception Criteria for Consent (Check if **"Yes."** All must be checked)

- ☐ The patient is (was) confronted by a life-threatening situation necessitating the use of the test article.
- ☐ Informed consent cannot (could not) be obtained from the patient because of an inability to communicate with, or obtain legally effective consent from, the patient.
- ☐ Time is (was) insufficient to obtain consent from the patient's LAR.
- ☐ There is (was) no available alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the life of the patient.
- ☐ The treating physician will document (has documented) in the medical record that the above findings were met.
- ☐ The treating physician will report (has reported) the use to the IRB within 5 days with documentation that the above findings were met.
- ☐ A physician uninvolved in the clinical investigation will certify (has certified) in the medical record that the above findings were met.
- ☐ A physician uninvolved in the clinical investigation will certify (has certified) to the IRB within 5 days that the above findings were met.
- ☐ If certification took place after the use of the drug or biologic, all of the following are true: **("N/A" if certification took place before the use)**
  - ☐ Immediate use of the test article is (was), in the physician's opinion, required to preserve the life of the patient.
  - ☐ There is (was) insufficient time to obtain the independent determination of a physician uninvolved in the clinical investigation.
  - ☐ The treating physician will document (has documented) in the medical record that the above findings were met.
  - ☐ The treating physician's report to the IRB within 5 days will document that the above findings were met.

[1] Emergency use of an unapproved drug or biologic is a clinical investigation and must comply with 21 CFR Part 50 and 21 CFR Part 56.
[2] If the treating physician believes s/he may need to use this test article in a similar emergency situation, s/he must submit a protocol for the use within 25 business days.

Emergency Use of an Unapproved Device[3]

4 Criteria for Emergency Use of an Unapproved Device (Check if **"Yes"** or **"N/A."** All must be checked)

- ☐ The patient is (was) confronted by a life-threatening disease or a serious condition requiring immediate use of the device.
- ☐ The situation necessitates (necessitated) the immediate use of the device.
- ☐ No generally acceptable alternative for treating the patient is (was) available.
- ☐ There is (was) insufficient time to use existing procedures to obtain FDA approval of an IDE.
- ☐ There is (was) substantial reason to believe that benefits will (would) exist.
- ☐ The treating physician will document (has documented) in the medical record that the above findings were met.
- ☐ The treating physician will report (has reported) the use to the IRB within 5 days with documentation that the above findings were met.
- ☐ A physician uninvolved in the emergency use will certify (has certified) in the medical record that the above findings were met.
- ☐ A physician uninvolved in the emergency use will certify (has certified) to the IRB within 5 days that the above findings were met.[4]
- ☐ One of the following is true:
  - ☐ There is (was) no IDE.
  - ☐ The treating physician wants (wanted) to use the device in a way not approved under an existing IDE.
  - ☐ The treating physician is (was) not part of the IDE study.
- ☐ One of the following is true:
  - ☐ There is an IDE and the treating physician has (had) authorization from the sponsor.
  - ☐ There is no IDE and the treating physician will notify (has notified) FDA of the emergency use within 5 days
- ☐ The use is (was) **NOT** subject to DHHS regulation See *OIA-310 WORKSHEET: Human Research Determination*, or equivalent.

Section 5 or 6 must be met

5 Consent Criteria (Check if **"Yes."** All must be checked)

- ☐ Informed consent will be (was) sought from the patient or the patient's LAR.[5]
- ☐ Informed consent will be (was) documented using *OIA-506 TEMPLATE CONSENT DOCUMENT: Expanded Access*, or equivalent.[6]

6 Exception Criteria for Consent (Check if **"Yes."** All must be checked)

- ☐ The patient is (was) confronted by a life-threatening situation necessitating the use of the test article.
- ☐ Informed consent cannot (could not) be obtained from the patient because of an inability to communicate with, or obtain legally effective consent from, the patient.
- ☐ Time is (was) insufficient to obtain consent from the patient's legal representative.
- ☐ There is (was) no available alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the life of the patient.
- ☐ The treating physician will document (has documented) in the medical record that the above findings were met.
- ☐ The treating physician will report (has reported) the use to the IRB within 5 days with documentation that the above findings were met.
- ☐ A physician uninvolved in the clinical investigation will certify (has certified) in the medical record that the above findings were met.
- ☐ A physician uninvolved in the clinical investigation will certify (has certified) to the IRB within 5 days that the above findings were met.
- ☐ If certification took place after the use of the drug or biologic, all of the following are true: **("N/A" if certification took place before the use)**
  - ☐ Immediate use of the test article is (was), in the physician's opinion, required to preserve the life of the patient
  - ☐ There is (was) insufficient time to obtain the independent determination of a physician uninvolved in the clinical investigation.
  - ☐ The treating physician will document (has documented) in the medical record that the above findings were met.
  - ☐ The treating physician's report to the IRB within 5 days will document that the above findings were met.

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[3] Under FDA regulations, the emergency use of a test article, other than a medical device, is a clinical investigation, the patient is a participant, and the FDA may require data from an emergency use to be reported in a marketing application.
FDA does not consider the emergency use of an unapproved device to be clinical investigation and FDA does not require compliance with 21 CFR Part 50 and 21 CFR Part 56. The requirements are based on FDA guidance at Emergency Use and Compassionate Use of Unapproved Devices (presentation), Expanded Access for Medical Devices, Frequently Asked Questions About Medical Devices, and Institutional Review Board (IRB) Review of Individual Patient Expanded Access Submissions for Investigational Drugs and Biological Products.

[4] This may take place before or after the use.

[5] FDA does not require the consent process to follow the informed consent requirements at 21 CFR Part 50.

[6] FDA does not require the documentation of consent to follow the informed consent requirements at 21 CFR 50.27.

Compassionate Use of an Unapproved Device Being Used Without an IDE[7]	
7	**Criteria for Compassionate Use of an Unapproved Device** (Check if **"Yes"** or **"N/A."** All must be checked)
☐	The patient is (was) confronted by a serious disease or condition.
☐	No generally acceptable alternative for treating, diagnosing, or monitoring the patient is (was) available.
☐	The probable risk to the patient is (was) not greater than the probable risk from the disease.
☐	The treating physician will document (has documented) in the medical record that the above findings were met.
☐	The treating physician will report (has reported) the use to the IRB within 5 days with documentation that the above findings were met.
☐	A physician uninvolved in the compassionate use will certify (has certified) in the medical record that the above findings were met.
☐	A physician uninvolved in the compassionate use will certify (has certified) to the IRB within 5 days that the above findings were met.
☐	The treating physician has concurrence from FDA for the use.
☐	All institutional clearances have been obtained.
☐	The treating physician will report any problems as a result of the device use to the IRB and sponsor.
☐	The treating physician will write a summary of the use and give it to the sponsor or the FDA.
☐	The use is (was) **NOT** subject to DHHS regulation. See *OIA-310 WORKSHEET: Human Research Determination*, or equivalent.
8	**Consent criteria** (Check if **"Yes."** All must be checked)
☐	Informed consent will be (was) sought from the patient or the patient's LAR.[8]
☐	Informed consent will be (was) documented using *OIA-506 TEMPLATE CONSENT DOCUMENT: Expanded Access*, or equivalent.[9]
Emergency Use of a Humanitarian Use Device (HUD) for Which a Humanitarian Device Exemption (HDE) Has Been Issued	
9	**Criteria for Emergency Use of HUD for Which an HDE Has Been Issued** (Check if **"Yes"** or **"N/A."** All must be checked)[10]
☐	The patient is (was) confronted by a serious disease or condition.
☐	No generally acceptable alternative for treating, diagnosing, or monitoring the patient is (was) available.
☐	The probable risk to the patient is (was) not greater than the probable risk from the disease
☐	The treating physician will document (has documented) in the medical record that the above findings were met.
☐	The treating physician will report (has reported) the use to the IRB within 5 days with documentation that the above findings were met.
☐	The treating physician's report includes the identification of the patient involved, the date of the use, and the reason for the use.[11]
10	**Consent criteria** (Check if **"Yes."** All must be checked)
☐	Informed consent will be (was) sought from the patient or the patient's LAR.[12]
☐	The informed consent process will disclose (disclosed), at a minimum, the following: • That the device is an HUD and that, although the device is authorized by federal law, the effectiveness of the device for the specific indication has not been demonstrated. • If the HUD will be (was) used outside the scope of the indication authorized in the HDE, that the use is outside of the indications for which the FDA has approved the use of the HUD.

[7] FDA does not consider the compassionate use of an unapproved device being used without an IDE to be a clinical investigation and FDA does not require compliance with 21 CFR Part 50 and 21 CFR Part 56. The requirements are based on FDA guidance at Emergency Use and Compassionate Use of Unapproved Devices (Presentation), Expanded Access for Medical Devices, Frequently Asked Questions About Medical Devices, and Institutional Review Board (IRB) Review of Individual Patient Expanded Access Submissions for Investigational Drugs and Biological Products.
[8] FDA does not require the consent process to follow the informed consent requirements at 21 CFR Part 50.
[9] FDA does not require the documentation of consent to follow the informed consent requirements at 21 CFR 50.27.
[10] Humanitarian Device Exemption (HDE) Program - Guidance for Industry and Food and Drug Administration Staff (fda.gov)
[11] 21 CFR 814.124(a)
[12] FDA does not require the consent process to follow the informed consent requirements at 21 CFR Part 50.